47

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,298	11/21/2001	Alan D. Schreiber	555-63	9500

23117 7590 04/05/2004

NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,298	SCHREIBER ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *23 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-25* is/are pending in the application.

4a) Of the above claim(s) *1,2,11-21 and 23-25* is/are withdrawn from consideration.

5)☒ Claim(s) *4* is/are allowed.

6)☒ Claim(s) *5-10 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2 and 4-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 12-23-2003 are acknowledged. Claims 4-10 and 22 have been amended. Claim 3 has been canceled. Claims 1-2, 11-21 and 23-25 remain withdrawn from consideration. Claims 4-10 and 22 are currently under examination.

Claim Rejections Withdrawn

The rejection of claim 3 and 4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 14-15 and 17 of U.S. Patent No. 5,776,910 in view of Downey et al. (Journal of Biological Chemistry Vol. 274, No. 40, pages 28436-28444, 1999 – IDS-6) is withdrawn in light of the amendment to claim 4 and the cancellation of claim 3.

The rejection of claims 3 and 4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 9-11 of U.S. Patent No. 6,068,983 in view of Downey et al. (Journal of Biological Chemistry Vol. 274, No. 40, pages 28436-28444, 1999 –IDS-6) is withdrawn in light of the amendment to claim 4 and the cancellation of claim 3.

The rejection of claims 3 and 4 under 35 U.S.C. 102(b) as being anticipated by Downey et al. (Journal of Biological Chemistry Vol. 274, No. 40, pages 28436-28444, 1999 – IDS-6) is withdrawn in light of the amendment to claim 4 and the cancellation of claim 3.

The rejection of claims 3 and 4 under 35 U.S.C. 102(b) as being anticipated by Schreiber et al. (U.S. Patent No. 5,776,910) is withdrawn in light of the amendment to claim 4 and the cancellation of claim 3.

The rejection of claims 3 and 4 under 35 U.S.C. 102(e) as being anticipated by Schreiber et al. (U.S. Patent No. 6,068,983) is withdrawn in light of the amendment to claim 4 and the cancellation of claim 3.

Claim Rejections Maintained and New Grounds of Rejection

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5-10 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 14-15 and 17 of U.S. Patent No. 5,776,910 in view of Downey et al. (Journal of Biological Chemistry Vol. 274, No. 40, pages 28436-28444, 1999 – IDS-6) for the reasons set forth in the previous Office action in the rejection of claims 3-10 and 22.

The instant invention is drawn to methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding **an** FcγRIIA receptor comprising at least one L-T-L peptide sequence in its cytoplasmic domain (claims 3-5). Said cells can normally express FcγRIIA (claims 6 and 8) or not normally express FcγRIIA (claims 7-8). Said nucleic

acid can be introduced into said cell via a liposome, a bacterium or a viral vector (claim 10). Finally, the claimed particle can be a bacterium (claim 9), an antibiotic resistant bacteria (claim 22) or a mycobacterium (claim 22).

Applicant argues:

1. The instant claims require an Fc receptor comprising I) a cytoplasmic domain of FcγRIIA modified to include at least 1 additional L-T-L or ii) a γ chain cytoplasmic domain modified to include at least one L-T-L.

2. The cited patent makes no mention of an L-T-L sequence nor does it suggest L-T-L sequences in the claimed environments.

Applicant's arguments have been fully considered and deemed non-persuasive. Since the L-T-L sequence (motif) is inherently present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif) it need not be explicitly disclosed. Therefore, the rejection is deemed proper and is maintained.

As outlined previously, U.S. Patent No. 5,776,910 recites claims drawn to a method of increasing phagocytosis of lung cells by introducing into cells via a viral vector, liposome or a non-infectious bacterium a DNA molecule coding for an Fc receptor (claims 1 and 7-9). Said Fc receptor can be an FcγRIIA receptor (claims 1, 14-15 and 17). Moreover, said cells may be normally phagocytic, i.e. normally express FcγRIIA, (claims 2-4) or normally non-phagocytic, i.e. normally do not express FcγRIIA (claims 5-6) It should be noted that the U.S. Patent 5,776,910 does not recite that the claimed Fc receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif). Moreover, while the methods disclosed in U.S.

Patent 5,776,910 read only on increasing the phagocytic activity of cells by the introduction of DNA coding for FcγRIIA, said methods induce an increased phagosomal maturation resulting in bactericidal capability (see Downey et al. page28441-28442). Finally, while methods recited in U.S. Patent 5,776,910 are not explicitly drawn to bacterium, an antibiotic resistant bacteria or a mycobacterium they are encompassed by claim 1 which is interpreted as being drawn to the phagocytosis of any "particle".

Claims 5-10 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 14-15 and 17 of U.S. Patent No. 6,068,983 in view of Downey et al. (Journal of Biological Chemistry Vol. 274, No. 40, pages 28436-28444, 1999 – IDS-6) for the reasons set forth in the previous Office action in the rejection of claims 3-10 and 22.

Applicant argues:

1. The instant claims require an Fc receptor comprising I) a cytoplasmic domain of FcγRIIA modified to include at least 1 additional L-T-L or ii) a γ chain cytoplasmic domain modified to include at least one L-T-L.

2. The cited patent makes no mention of an L-T-L sequence nor does it suggest L-T-L sequences in the claimed environments.

Applicant's arguments have been fully considered and deemed non-persuasive. Since the L-T-L sequence (motif) is inherently present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif) it need not be explicitly disclosed. Therefore, the rejection is deemed proper and is maintained.

As outlined previously, U.S. Patent No. 6,068,983 recites claims drawn to a method of increasing phagocytosis of lung cells by introducing into cells via a viral vector, liposome or a non-infectious bacterium a DNA molecule coding for an Fc receptor (claims 1 and 9-11). Moreover, said cells may be normally phagocytic, i.e. normally express Fc receptors, i.e. FcγRIIA, (claims 2-4) or normally non-phagocytic, i.e. normally do not express Fc receptors, i.e. FcγRIIA (claims 5-6, 8) It should be noted that the U.S. Patent 6,068,983 does not recite that the claimed Fc receptor is FcγRIIA or that said receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif) and FcγRIIA is encompassed by the broadly recited genus of Fc receptors. Moreover, while the methods disclosed in U.S. Patent 6,068,983 read only on increasing the phagocytic activity of cells by the introduction of DNA coding for an Fc receptor, said methods induce an increased phagosomal maturation resulting in bactericidal capability (see Downey et al. pages 28441-28442). Finally, while methods recited in U.S. Patent 6,068,983 are not explicitly drawn to bacterium, an antibiotic resistant bacteria or a mycobacterium they are encompassed by claim 1 which is interpreted as being drawn to the phagocytosis of any "particle".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Downey et al. (Journal of Biological Chemistry Vol. 274, No. 40, pages 28436-28444, 1999 – IDS-6) for the reasons set forth in the previous Office action in the rejection of claims 3-5 and 7-10.

The instant invention is drawn to methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding an FcγRIIA receptor comprising at least one L-T-L peptide sequence in its cytoplasmic domain (claims 3-5) into said cells wherein said cells do not normally express FcγRIIA (claims 7-8). Said nucleic acid can be introduced into said cell via a liposome, a bacterium or a viral vector (claim 10). Finally, the claimed particle can be a bacterium (claim 9).

Applicant argues:

1. Downey et al. neither teaches nor suggests modified receptors of the type recited in the claims.

Applicant's arguments have been fully considered and deemed non-persuasive. As reiterated above, FcγRIIA inherently possesses a L-T-L sequence (motif) in its cytoplasmic domain. Consequently, Downey anticipates the instant invention since the rejected claims read on methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding an FcγRIIA receptor comprising a single L-T-L peptide sequence in its cytoplasmic domain.

As outlined previously, Downey et al. disclose methods for transfecting FcγRIIA into non-myloid cells (see page 28437). Said methods conferring on said cells not only particle internalization (phagocytosis) but also phagosomal maturation and acidification. Said phagolysosomes were further disclosed to limit the growth of internalized microorganisms (see pages 28441-28442). It should be noted that Downey et al. do not explicitly disclose that the claimed Fc receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif).

Claims 5-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Schreiber et al. (U.S. Patent No. 5,776,910) for the reasons set forth in the previous Office action in the rejection of claims 3-8 and 10.

The instant invention is drawn to methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding an FcγRIIA receptor comprising at least one L-T-L peptide sequence in its cytoplasmic domain (claims 3-5). Said cells can normally express FcγRIIA (claims 6 and 8) or not normally express FcγRIIA (claims 7-8). Said nucleic acid can be introduced into said cell via a liposome, a bacterium or a viral vector (claim 10).

Applicant argues:

1. Schreiber et al. is silent with regard to an L-T-L sequence and in no way teaches (inherently or explicitly), modified receptors of the types recited in the instant claims.

Applicant's arguments have been fully considered and deemed non-persuasive. As reiterated above, FcγRIIA inherently possesses a L-T-L sequence (motif) in its cytoplasmic domain. Consequently, Downey anticipates the instant invention since the rejected claims read on methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding an FcγRIIA receptor comprising a single L-T-L peptide sequence in its cytoplasmic domain.

As outlined previously, Schreiber et al. disclose methods of modulating the phagocytic potential of cells that are naturally phagocytic (e.g. macrophages) and methods of rendering cells phagocytic that do not naturally possess that function (see column 4, lines 48-52). Schreiber et al. further disclose that said methods provide innovative treatment regimens that can be used to combat infections (see column 4, lines 52-54). Said methods comprise introducing into cells via a viral vector, liposome or a non-infectious bacterium a DNA molecule coding for an Fc receptor (see column 10 lines 24-27 and column 10, line 63 to column 11, line 1). Moreover, Schreiber et al. disclose that said Fc receptor could be an FcγRIIA receptor (see Example II). It should be noted that Schreiber et al. do not explicitly disclose that the claimed Fc receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif). Moreover, while the methods disclosed by Schreiber et al. read only on increasing the phagocytic activity of cells by the introduction of DNA coding for FcγRIIA, said methods induce an increased phagosomal maturation resulting in bactericidal capability.

Claims 5-8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Schreiber et al. (U.S. Patent No. 6,068,983) for the reasons set forth in the previous Office action in the rejection of claims 3-8 and 10.

The instant invention is drawn to methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding an FcγRIIA receptor comprising at least one L-T-L peptide sequence in its cytoplasmic domain (claims 3-5). Said cells can normally express FcγRIIA (claims 6 and 8) or not normally express FcγRIIA (claims 7-8). Said nucleic acid can be introduced into said cell via a liposome, a bacterium or a viral vector (claim 10).

Applicant argues:

1. The cited reference says nothing of L-T-L sequences and cannot be viewed as teaching or suggesting modified receptors of the type recited in the instant claims.

Applicant's arguments have been fully considered and deemed non-persuasive. As reiterated above, FcγRIIA inherently possesses a L-T-L sequence (motif) in its cytoplasmic domain. Consequently, Downey anticipates the instant invention since the rejected claims read on methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding an FcγRIIA receptor comprising a single L-T-L peptide sequence in its cytoplasmic domain.

As outlined previously, Schreiber et al. disclose methods of modulating the phagocytic potential of cells that are naturally phagocytic (e.g. macrophages) and methods of rendering cells phagocytic that do not naturally possess that function (see column 4, lines 48-52). Schreiber et al.

further disclose that said methods provide innovative treatment regimens that can be used to combat infections (see column 4, lines 52-54). Said methods comprise introducing into cells via a viral vector, liposome or a non-infectious bacterium a DNA molecule coding for an Fc receptor (see column 10 lines 24-27 and column 10, line 63 to column 11, line 1). Moreover, Schreiber et al. disclose that said Fc receptor could be an FcγRIIA receptor (see Example II). It should be noted that Schreiber et al. do not explicitly disclose that the claimed Fc receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif). Moreover, while the methods disclosed by Schreiber et al. read only on increasing the phagocytic activity of cells by the introduction of DNA coding for FcγRIIA, said methods induce an increased phagosomal maturation resulting in bactericidal capability.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is rendered vague and indefinite by the use of the phrase "cytoplasmic domain modified to comprise at least one L-T-L peptide". It is unclear why said domain would have to be modified since it inherently possesses one L-T-L motif. As written, it is impossible to determine the metes and bounds of the claimed invention.

Conclusion

Claim 4 is allowed.

Claims 6-10 would be allowable if they were amended to depend only on claim 4.

Claims 5-10 and 22 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
April 1, 2004

L. F. Smith

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1645